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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,942	01/30/2004	William Robert Wilson	3911-21	4280
23117	7590	11/29/2007		
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER SUTTON, DARRYL C	
			ART UNIT 1614	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/766,942

Applicant(s)

WILSON ET AL.

Examiner

Darryl C. Sutton

Art Unit

4133

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-73 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to a cytotoxic synergistic composition of an effective amount of a compound of formula A or pharmaceutically acceptable salt thereof where Z= N and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where Z=N, classified in class 514, subclass various.
- II. Claims 1-6 drawn to a cytotoxic synergistic composition of an effective amount of a compound of formula A or pharmaceutically acceptable salt thereof where Z= CCN and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where Z=N, classified in class 514, subclass various.
- III. Claims 1-6 drawn to a cytotoxic synergistic composition of an effective amount of a compound of formula A or pharmaceutically acceptable salt thereof where Z= CCN and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where Z=CCN, classified in class 514, subclass various.
- IV. Claims 1-6 drawn to a cytotoxic synergistic composition of an effective amount of a compound of formula A or pharmaceutically acceptable salt thereof where Z= N and an effective amount of a compound of formula B

or pharmaceutically acceptable salt thereof where  $Z=CCN$ , classified in class 514, subclass various.

- V. Claims 7-12, drawn to a method of treating a subject in need of cancer therapy comprising administering a cytotoxic effective amount of a composition of a compound of formula A or pharmaceutically acceptable salt thereof where  $Z= N$  and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where  $Z=N$ , classified in class 424, subclass 115.1
- VI. Claims 7-12, drawn to a method of treating a subject in need of cancer therapy comprising administering a cytotoxic effective amount of a composition of a compound of formula A or pharmaceutically acceptable salt thereof where  $Z= CCN$  and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where  $Z=N$ , classified in class 514, subclass various.
- VII. Claims 7-12, drawn to a method of treating a subject in need of cancer therapy comprising administering a cytotoxic effective amount of a composition of a compound of formula A or pharmaceutically acceptable salt thereof where  $Z= CCN$  and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where  $Z=CCN$ , classified in class 514, subclass various.
- VIII. Claims 7-12, drawn to a method of treating a subject in need of cancer therapy comprising administering a cytotoxic effective amount of a

composition of a compound of formula A or pharmaceutically acceptable salt thereof where  $Z = N$  and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where  $Z = CCN$ , classified in class 514, subclass various.

- IX. Claims 13-18, drawn to a compound of formula I, where  $Z = N$ , classified in class 514, subclass various.
- X. Claims 13-18, drawn to a compound of formula I, where  $Z = CCN$ , classified in class 514, subclass various
- XI. Claims 19-23, drawn to a method of treating a subject in need of cancer therapy comprising the steps of administering a cytotoxic effective amount of a compound of formula I, where  $Z = N$ , classified in class 514, subclass various.
- XII. Claims 19-23, drawn to a method of treating a subject in need of cancer therapy comprising the steps of administering a cytotoxic effective amount of a compound of formula I, where  $Z = CCN$ , classified in class 514, subclass various.
- XIII. Claims 24-28, drawn to compound of formula I', where  $Z = N$  and  $Z' = N$ , classified in class 514, subclass various.
- XIV. Claims 24-28, drawn to compound of formula I', where  $Z = CCN$  and  $Z' = N$ , classified in class 514, subclass various.

Art Unit: 4133

- XV. Claims 24-28, drawn to compound of formula I', where  $Z=CCN$  and  $Z'=CCN$ , classified in class 514, subclass various.
- XVI. Claims 24-28, drawn to compound of formula I', where  $Z=N$  and  $Z'=CCN$ , classified in class 514, subclass various.
- XVII. Claims 29-33, drawn to a method of treating a subject in need of cancer therapy comprising administering a cytotoxic effective amount of a compounds of formula I', where  $Z=N$  and  $Z'=N$ , classified in class 514, subclass various
- XVIII. Claims 29-33, drawn to a method of treating a subject in need of cancer therapy comprising administering a cytotoxic effective amount of a compounds of formula I', where  $Z=CCN$  and  $Z'=N$ , classified in class 514, subclass various.
- XIX. Claims 29-33, drawn to a method of treating a subject in need of cancer therapy comprising administering a cytotoxic effective amount of a compounds of formula I', where  $Z=CCN$  and  $Z'=CCN$ , classified in class 514, subclass various.
- XX. Claims 29-33, drawn to a method of treating a subject in need of cancer therapy comprising administering a cytotoxic effective amount of a compounds of formula I', where  $Z=N$  and  $Z'=CCN$ , classified in class 514, subclass various.
- XXI. Claims 34-44, drawn to a compound of formula II, where  $Z=N$ , classified in class class 514, subclass various.

- XXII. Claims 34-44, drawn to a compound of formula II, where  $Z=CCN$ , classified in class 514, subclass various.
- XXIII. Claims 45-49, drawn to a method of treating a subject in need of cancer therapy comprising administering a cytotoxic effective amount of a compound of formula II, where  $Z=N$ , classified in class 514, subclass various.
- XXIV. Claims 45-49, drawn to a method of treating a subject in need of cancer therapy comprising administering a cytotoxic effective amount of a compound of formula II, where  $Z=CCN$ , classified in class 514, subclass various.
- XXV. Claims 50-60, drawn to a compound of formula II', where  $Z=N$ , classified in class 514, subclass various.
- XXVI. Claims 50-60, drawn to a compound of formula II', where  $Z=CCN$ , classified in class 514, subclass various.
- XXVII. Claims 61-65, drawn to a method of treating a subject in need of cancer therapy comprising administering a cytotoxic effective amount of a compound of formula II', where  $Z=N$ , classified in class 514, subclass various.
- XXVIII. Claims 61-65, drawn to a method of treating a subject in need of cancer therapy comprising administering a cytotoxic effective amount of a compound of formula II', where  $Z=CCN$ , classified in class 514, subclass various.

XXIX. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an amount of a compound of formula B or pharmaceutically acceptable salt thereof where  $Z=N$ , that has been administered to a subject in need of cancer therapy comprised of administering a compound of formula A or pharmaceutically acceptable salt thereof where  $Z= N$  classified in class 514, subclass various.

XXX. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an amount of a compound of formula B or pharmaceutically acceptable salt thereof where  $Z=N$ , that has been administered to a subject in need of cancer therapy comprised of administering a compound of formula A or pharmaceutically acceptable salt thereof where  $Z= CCN$  classified in class 514, subclass various.

XXXI. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an amount of a compound of formula B or pharmaceutically acceptable salt thereof where  $Z=CCN$ , that has been administered to a subject in need of cancer therapy comprised of administering a compound of formula A or pharmaceutically acceptable salt thereof where  $Z= CCN$  classified in class 514, subclass various.

XXXII. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an amount of a compound of formula B or pharmaceutically acceptable salt



thereof where  $Z=CCN$ , that has been administered to a subject in need of cancer therapy comprised of administering a compound of formula A or pharmaceutically acceptable salt thereof where  $Z= N$  classified in class 514, subclass various.

XXXIII. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an amount of a cytotoxic synergistic composition of an effective amount of a compound of formula A or pharmaceutically acceptable salt thereof where  $Z= N$  and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where  $Z=N$ , that has been administered to a subject in need of cancer therapy comprised of administering a cytotoxic synergistic composition of an effective amount of a compound of formula A or pharmaceutically acceptable salt thereof where  $Z= N$  and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where  $Z=N$ , classified in class 514, subclass various.

XXXIV. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an amount of a cytotoxic synergistic composition of an effective amount of a compound of formula A or pharmaceutically acceptable salt thereof where  $Z= N$  and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where  $Z=N$ , that has been administered to a subject in need of cancer therapy comprised of administering a cytotoxic synergistic composition of an effective amount of

Art Unit: 4133

a compound of formula A or pharmaceutically acceptable salt thereof  
where Z= CCN and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=N, classified in class  
514, subclass various.

XXXV. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
Z=N and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=N, that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of  
a compound of formula A or pharmaceutically acceptable salt thereof  
where Z= CCN and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=CCN, classified in class  
514, subclass various.

XXXVI. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
Z= N and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=N, that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of

a compound of formula A or pharmaceutically acceptable salt thereof  
where  $Z = N$  and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where  $Z = CCN$ , classified in class  
514, subclass various.

XXXVII. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
 $Z = CCN$  and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where  $Z = N$ , that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of  
a compound of formula A or pharmaceutically acceptable salt thereof  
where  $Z = N$  and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where  $Z = N$ , classified in class  
514, subclass various.

XXXVIII. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
 $Z = CCN$  and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where  $Z = N$ , that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of

Art Unit: 4133

a compound of formula A or pharmaceutically acceptable salt thereof  
where Z= CCN and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=N, classified in class  
514, subclass various.

XXXIX. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
Z= CCN and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=N, that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of  
a compound of formula A or pharmaceutically acceptable salt thereof  
where Z= CCN and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=CCN, classified in class  
514, subclass various.

XXXX. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
Z= CCN and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=N, that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of

a compound of formula A or pharmaceutically acceptable salt thereof  
where  $Z = N$  and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where  $Z = CCN$ , classified in class  
514, subclass various.

XXXXI. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
 $Z = CCN$  and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where  $Z = CCN$ , that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of  
a compound of formula A or pharmaceutically acceptable salt thereof  
where  $Z = N$  and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where  $Z = N$ , classified in class  
514, subclass various.

XXXXII. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
 $Z = CCN$  and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where  $Z = CCN$ , that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of

Art Unit: 4133

a compound of formula A or pharmaceutically acceptable salt thereof  
where Z= CCN and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=N, classified in class  
514, subclass various.

XXXXIII. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
Z= CCN and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=CCN, that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of  
a compound of formula A or pharmaceutically acceptable salt thereof  
where Z= CCN and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=CCN, classified in class  
514, subclass various.

XXXXVIII. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
Z= CCN and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=CCN, that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of

a compound of formula A or pharmaceutically acceptable salt thereof  
where  $Z = N$  and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where  $Z = CCN$ , classified in class  
514, subclass various.

XXXXV. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
 $Z = N$  and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where  $Z = CCN$ , that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of  
a compound of formula A or pharmaceutically acceptable salt thereof  
where  $Z = N$  and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where  $Z = N$ , classified in class  
514, subclass various.

XXXXVI. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
 $Z = N$  and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where  $Z = CCN$ , that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of

Art Unit: 4133

a compound of formula A or pharmaceutically acceptable salt thereof  
where Z= CCN and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=N, classified in class  
514, subclass various.

XXXXVII. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
Z=N and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=CCN, that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of  
a compound of formula A or pharmaceutically acceptable salt thereof  
where Z= CCN and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=CCN, classified in class  
514, subclass various.

XXXXVIII. Claims 66-69, drawn to a method of potentiating the cytotoxicity of an  
amount of a cytotoxic synergistic composition of an effective amount of a  
compound of formula A or pharmaceutically acceptable salt thereof where  
Z=N and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=CCN, that has been  
administered to a subject in need of cancer therapy comprised of  
administering a cytotoxic synergistic composition of an effective amount of



a compound of formula A or pharmaceutically acceptable salt thereof  
where Z= N and an effective amount of a compound of formula B or  
pharmaceutically acceptable salt thereof where Z=CCN, classified in class  
514, subclass various.

XXXXIX. Claims 70-73, drawn to a method of potentiating the cytotoxicity of one  
or more chemotherapeutic agents administered to a subject comprised of  
further administering a compound of formula A, where Z=N classified in  
class 514, subclass various.

L. Claims 70-73, drawn to a method of potentiating the cytotoxicity of one or  
more chemotherapeutic agents administered to a subject comprised of  
further administering a compound of formula A, where Z=CCN classified in  
class 514, subclass various.

LI. Claims 70-73, drawn to a method of potentiating the cytotoxicity of one or  
more chemotherapeutic agents administered to a subject comprised of  
further administering a cytotoxic synergistic composition of an effective  
amount of a compound of formula A or pharmaceutically acceptable salt  
thereof where Z= N and an effective amount of a compound of formula B  
or pharmaceutically acceptable salt thereof where Z=N classified in class  
514, subclass various.

LII. Claims 70-73, drawn to a method of potentiating the cytotoxicity of one or  
more chemotherapeutic agents administered to a subject comprised of  
further administering a cytotoxic synergistic composition of an effective

amount of a compound of formula A or pharmaceutically acceptable salt thereof where Z= CCN and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where Z=N classified in class 514, subclass various.

- LIII. Claims 70-73, drawn to a method of potentiating the cytotoxicity of one or more chemotherapeutic agents administered to a subject comprised of further administering a cytotoxic synergistic composition of an effective amount of a compound of formula A or pharmaceutically acceptable salt thereof where Z= CCN and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where Z=CCN classified in class 514, subclass various.
- LIV. Claims 70-73, drawn to a method of potentiating the cytotoxicity of one or more chemotherapeutic agents administered to a subject comprised of further administering a cytotoxic synergistic composition of an effective amount of a compound of formula A or pharmaceutically acceptable salt thereof where Z= N and an effective amount of a compound of formula B or pharmaceutically acceptable salt thereof where Z=CCN classified in class 514, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Groups I-IV, IX, X, XIII-XVI and XXI- XXVI are independent and distinct from each other as they are drawn to compounds of formula A, B, I, I', II and II' with different divergent moieties in the Z, Z', J, T, X, X', W, Y<sub>1</sub>, Y<sub>2</sub>, Y<sub>3</sub>, Y<sub>4</sub> and A positions. Each of groups I-IV, IX, X, XIII-XVI and XXI- XXVI are directed to compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of actions, different effects, and reactive conditions. It is noted that a reference disclosing a compound of one group would not necessarily disclose a compound of the other groups. Additionally, the level of skill in the art is not such that one invention would be obvious over the other, i.e. they are patentable over each other. Chemical structures that are similar are presumed to function similarly, while chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Thus, by virtue of the different structures presented in I-IV, IX, X, XIII-XVI and XXI- XXVI these inventions are distinct.

Inventions I I-IV, IX, X, XIII-XVI and XXI- XXVI and inventions V-VIII, XI, XII, XVII-XX and XXVII-LIV are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

Art Unit: 4133

product. See MPEP § 806.05(h). In the instant case since the compounds have a cytotoxic effect in conditions of low oxygen the compositions and/or compounds of Groups I-IV, IX, X, XIII-XVI and XXI- XXVI could be used for screening tissue for hypoxia, as in conditions such as rheumatoid arthritis and diabetes.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species: (a) atoms or groups J, T and the position of J and of T on the benzene rings of formula and of formula B, (b) position of O<sup>-</sup> in formula A (c) atom W on both formula A and on formula B, (d) groups Y<sub>1</sub> and Y<sub>2</sub> and the position each on compound of formula I, (e) the position of O<sup>-</sup> on formula I, (f) group X of formula I, (g) A of formula I, (h) Y<sub>1</sub>, Y<sub>2</sub>, Y<sub>3</sub>, Y<sub>4</sub> and their position in formula I', (i) X and X' on formula I', (j) position of both O<sup>-</sup> moieties on formula I', (k) n = (1 or 2) on formula I', (l) A on formula I', (m) Y<sub>1</sub> and Y<sub>2</sub> and their positions on formula II, (n) the position of O<sup>-</sup> on formula II, (o) X on formula II, (p) A on formula II, (q) DNA targeting unit on formula II, (r) Y<sub>5</sub> on formula II', (s) position of O<sup>-</sup> on formula II', (t) Y<sub>1</sub> and X and their positions on formula II', (u) A on formula II', (v) the DNA targeting unit on formula II', (w) chemotherapeutic agent or treatment or combinations thereof. The species are independent or distinct because due to significant variation in each of the claimed genus of compounds, a comprehensive search of any one compound in a group would not necessarily be a coextensive search for any one or more of the other compounds in that group; each of the chemotherapeutic agent or treatments is distinct and has a distinct physiological effect on the body.

If the applicant elects one of Groups I-VIII, then an election of **each** of (a) the atoms or groups J and T and their positions on formula A and formula B, (b) the position of O<sup>-</sup> in formula A, and (c) W on formula A and formula B must also be made.

If the applicant elects one of Groups IX-XII, then an election of **each** of (d) groups  $Y_1$  and  $Y_2$  and the position each on compound of formula I, (e) the position of  $O^-$  on formula I, (f) group X of formula I, and (g) A of formula I must also be made.

If the applicant elects one of Groups XIII-XX, then an election of **each** of (h)  $Y_1$ ,  $Y_2$ ,  $Y_3$ ,  $Y_4$  and their position in formula I', (i) X and X' on formula I', (j) position of both  $O^-$  moieties on formula I', (k) n (= 1 or 2) on formula I', and (l) A on formula I' must also be made.

If the applicant elects one of Groups XXI-XXIV, then an election of **each** of (m)  $Y_1$  and  $Y_2$  and their positions on formula II, (n) the position of  $O^-$  on formula II, (o) X on formula II, (p) A on formula II, and (q) DNA targeting unit on formula II must also be made.

If the applicant elects one of Groups XXV-XXVIII, then an election of **each** of (r)  $Y_5$  on formula II', (s) position of  $O^-$  on formula II', (t)  $Y_1$  and X and their positions on formula II', (u) A on formula II', and (v) the DNA targeting unit on formula II' must also be made. Optionally, an election of (w) chemotherapeutic agent or treatment or combinations thereof can also be made.

If the applicant elects one of Groups XXIX-XXXVIII, then an election of **each** of (a) the atoms or groups J and T and their positions on formula A and formula B, (b) the position of  $O^-$  in formula A, (c) W on formula A and formula B, and **optionally**, (w) chemotherapeutic agent or treatment or combinations thereof can also be made.

If the applicant elects one of Groups XXXIX-L, then an election of **each** of (a) the atoms or groups J and T and their positions on formula A, (b) the position of  $O^-$  in

Art Unit: 4133

formula A, (c) W on formula A, and (w) chemotherapeutic agent or treatment or combinations thereof can also be made.

If the applicant elects on of Groups LI-LIV, then an election of **each** of (a) atoms or groups J, T and the position of J and of T on the benzene rings of formula and of formula B, (b) position of O<sup>-</sup> in formula A (c) atom W on both formula A and on formula B, and (w) chemotherapeutic agent or treatment or combinations thereof can also be made.

Applicant is required to disclose all substituents and their positions in the formulas of the elected species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-73 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).



The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

Art Unit: 4133

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 4133

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and Fr from 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on M-Th from 8:00AM-4:00PM EST at (571)272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

DCS

  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER